

United States District Court
District of Massachusetts

_____)	
CARDIOFOCUS, INC.,)	
Plaintiff,)	
)	
v.)	Civil No.
)	08-10285-NMG
CARDIOGENESIS CORPORATION,)	
Defendant.)	
_____)	

MEMORANDUM & ORDER

GORTON, J.

This is a patent infringement action involving laser catheter systems. The Court held a Markman hearing on October 21, 2011, at which counsel offered arguments in support of their proposed claim constructions of disputed terms. The following is the Court's ruling with respect to those terms.

I. Patent Subject Matter

Plaintiff CardioFocus, Inc. ("CardioFocus") alleges that defendant Cardiogenesis Corporation ("Cardiogenesis") manufactured, used, imported, sold and offered for sale lasers that infringed at least one of its two patents-at-issue: U.S. Patent Nos. 5,843,073 ("the '073 patent") and 6,547,780 ("the '780 patent"). The '780 and '073 patents describe a system for transmitting laser energy to a surgical site via an optical fiber to repair or remove biological tissue. The invention is based,

in part, on the discoveries that 1) the wavelengths of infrared radiation emitted by so-called "rare earth" lasers, or lasers with a wavelength between 1.4 and 2.2 micrometers, are strongly absorbed in biological tissue and 2) low hydroxyl ion content silica fibers have the flexibility and high conductivity to enable the transmission of such wavelengths to remote surgical sites to facilitate repair or removal of biological tissue.

II. Claim Construction

A. Principles of Claim Construction

In analyzing a patent infringement action, a Court must 1) determine the meaning and scope of the patent claims asserted to be infringed and 2) compare the properly construed claims to the infringing device. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The first step, known as claim construction, is an issue of law for the court to decide. Id. at 979. The second step is determined by the finder of fact. Id.

The Court's responsibility is to determine the meaning of claim terms as they would be understood by persons of ordinary skill in the relevant art. Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001).

The patent specification is

the single best guide to the meaning of a disputed term [because it may reveal] a special definition given to a claim term that differs from the meaning it would otherwise possess [or contain] an intentional disclaimer, or disavowal, of claim scope by the inventor.

Phillips v. AWK Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The Court should also consult the prosecution history to see how the inventor and PTO understood the patent and to ensure the patentee does not argue in favor of an interpretation it has disclaimed. Id. at 1317.

In the rare event that analysis of the intrinsic evidence does not resolve an ambiguity in a disputed claim term, the Court may turn to extrinsic evidence, such as inventor and expert testimony, treatises and technical writings. Id. at 1314. Although extrinsic evidence may be helpful in construing claims, the intrinsic evidence is afforded the greatest weight in determining what a person of ordinary skill would have understood a claim to mean. Id. at 1324.

B. Disputed terms

CardioFocus alleges infringement of two claims of the '073 patent (Claims 2 and 7) and one claim of the '780 patent (Claim 2). Because the '780 Patent is a continuation-in-part of the '073 Patent, similar terms, used consistently, will be construed uniformly throughout both patents. See Epcon Gas Sys., Inc. v. Baur Compressors, Inc., 279 F.3d 1022, 1030-31 (Fed. Cir. 2002) ("[T]he same term or phrase should be interpreted consistently [when used as such] where it appears in claims of common ancestry."). Likewise, the same term or phrase, if used consistently in one or more claims, will be given the same

meaning throughout. See id. For purposes of context, the disputed claims are set forth fully below with the disputed terms highlighted the first time they appear:

U.S. Patent No. 6,547,780 (Claim 2)

The system of claim 1 [A surgical system comprising: a **hollow elongate surgical instrument, having at least one lumen** for receiving an optical fiber, and being maneuverable to provide a conduit for transmission of laser energy to a surgical site; and a **flexible, elongate fiber** for conducting laser energy from a proximal end of said fiber to a surgical site at a distal end of said fiber, the proximal end for receiving laser energy, and said fiber being a silica fiber including **means for reducing absorption of laser energy** at a wavelength of about 1.4 - 2.2 micrometers], wherein said fiber is suitable for **coupling with** and conducting energy of a Holmium-doped Yttrium-Aluminum-Garnet laser.

U.S. Patent No. 5,843,073 (Claim 2)

The system of claim 1 [A **system for transmitting laser energy via a [sic] optical fiber to a surgical site** comprising: a laser energy source operating at a wavelength in a range of about 1.4 - 2.2 micrometers; and a flexible elongate optical fiber for conducting laser energy from a proximal end of said fiber to a surgical site at a distal end of said fiber, the proximal end being **coupled to the output of said laser energy source**, and said fiber being a silica fiber having a **low hydroxyl ion content** to reduce absorption of said laser energy during transmission through said fiber], wherein said laser source comprises a Holmium-doped Yttrium-Aluminum-Garnet laser.

U.S. Patent No. 5,843,073 (Claim 7)

The system of claim 1 [A **system for transmitting laser energy via a [sic] optical fiber to a surgical site** comprising: a laser energy source operating at a wavelength in a range of about 1.4 - 2.2 micrometers; and a flexible elongate optical fiber for conducting laser energy from a proximal end of said fiber to a surgical site at a distal end of said fiber, the proximal end

being coupled to the output of said laser energy source, and said fiber being a silica fiber having a low hydroxyl ion content to reduce absorption of said laser energy during transmission through said fiber], wherein said laser source operates to deliver energy at a wavelength in a range of about 2.06 - 2.1 micrometers.

C. Claim Construction

1. "a hollow elongate surgical instrument having at least one lumen" ('780 Patent, Claim 2)

Cardiogenesis proposes that the claim terms be construed to mean:

A hollow, tubular and flexible instrument that can be selectively positioned within the body and can deploy an optical fiber therethrough for use in surgical procedures.

It reasons syllogistically that because claim 12 reads, "The system of claim 1 wherein the hollow elongate instrument is a catheter," and catheters are tubular and flexible, that the phrase "a hollow elongate surgical instrument having at least one lumen" must be construed to include the terms "tubular" and "flexible."

Such a construction would, however, violate the doctrine of claim differentiation by rendering dependent claims superfluous. Clearstream Wastewater Sys., Inc. v. Hydro-Action, Inc., 206 F.3d 1440, 1446-47 (Fed. Cir. 2000) (explaining that the doctrine "prevents the narrowing of broad claims by reading into them the limitations of narrower claims"). If the Court were to read the characteristics of a catheter into the terms of claim 2, reference to a catheter later in claim 12 would be redundant.

Neither the claim terms nor anything else in the intrinsic record demonstrates that the described surgical instrument is necessarily "tubular" or "flexible." While some of the figures in the specification possess those qualities, it would be improper to import a limitation from such embodiments into the claims of the patent. See Phillips, 415 F.3d at 1323. Notably, when Dr. Sinofsky intended a claim element to recite further limitations such as "flexible," he did so expressly. See, e.g., '780 patent, col. 9:7 (describing "a flexible, elongated fiber").

The claim terms do not implicate any special knowledge possessed by a person in the art and, thus, should be given their ordinary meanings. The terms "hollow" and "surgical instrument" are not sufficiently ambiguous or uncommon to warrant construction. As the Federal Circuit explained:

The Markman decisions do not hold that the trial judge must repeat or restate every claim term. . . . Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy.

U.S. Surgical Corp., v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997). In contrast, "elongate" and "lumen" are not used in common parlance and will be construed in accordance with their ordinary meanings of "long in proportion to width" and "hole," respectively. See Phillips, 415 F.3d at 1314 (explaining that in cases where an unambiguous claim term has no special meaning in

the field of art but its ordinary meaning may not be evident to a juror, the Court may consult a general purpose dictionary in construing it).

In sum, the Court will construe "a hollow elongate surgical instrument having at least one lumen" to mean: "a hollow surgical instrument, long in proportion to width, having at least one hole."

2. "a flexible, elongate fiber" ('780 Patent, Claim 2), and "a flexible, elongate optical fiber" ('073 Patent, Claim 7)

Cardiogenesis argues that the terms should be defined as:

A single, continuous, and flexible segment of silica fiber positioned to extend from the laser source to the surgical site.

CardioFocus counters that the terms should be given their ordinary meanings. Both parties agree that "fiber" should be construed to mean "silica fiber," consistent with the specification. The dispute is over whether the patent necessarily requires a "single" fiber and whether it must run "continuous . . . from the laser source to the surgical site."

a. Single

A customary principle of patent construction and the plain language of the specification counsel against construing the claim terms to include the word "single." In an open-ended claim containing the transitional phrase "comprising," such as the one here, the words "single", "a" or "an" should be construed to mean "one or more." Free Motion Fitness, Inc. v. Cybex Int'l, Inc.,

423 F.3d 1343, 1350 (Fed. Cir. 2005). That rule of patent construction is overcome only "when the claim is specific as to the number of elements" or "when the patentee evinces a clear intent to limit the article," id. at 1350, neither of which is the case here.

On the contrary, the patent language plainly contemplates the use of multiple fibers. The abstracts for both patents state: "The catheter may be comprised of a single optical fiber or a plurality of optical fibers." That language is echoed throughout the specifications, e.g., '780 patent, col. 7:57-58 ("the four optical fibers which pass through the catheter"); '073 patent, col. 8:42 ("the diverging beam from each of the fibers"), and reflected by the embodiments described in Figures 7-11 of the '780 patent, each of which depicts a four-fiber catheter. There is no indication that the patentee intended to limit the patents to a "single" fiber and the Court declines to read such a limitation into the patent.

b. Continuous

Cardiogenesis points to the surrounding claim terms and the prosecution history to support its argument that the phrase should be construed to include the word "continuous." First, defendant notes that the claim terms "a flexible, elongate optical fiber" were not written in isolation but rather constitute the start of a phrase that continues,

for conducting laser energy from a proximal end of said fiber to a surgical site at a distal end of said fiber, the proximal end being coupled to the output of said laser energy source . . .

Thus, Cardiogenesis asserts, even if the patent contemplates the use of a plurality of fibers, those fibers must be continuous if they conduct laser energy from their proximal to their distal ends.

Second, Cardiogenesis contends that the patentee relied on the invention's continuous fiber optic cable to distinguish claims 2 and 7 of the '073 patent from the Goldman prior art reference, which described a laser generator "far-removed from the surgical site." In light of such reliance, it argues, the Court should narrowly construe the otherwise broad claim language, citing for that proposition Seachange Int'l, Inc. v. C-Cor, Inc., 413 F.3d 1361, 1373 (Fed. Cir. 2005) ("[W]here an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of the otherwise broad claim language.").

Neither argument is persuasive. The reference to the proximal and distal ends of the fiber is understood by the Court to convey that the system was designed to transmit laser energy from the laser source all the way to the surgical site, not that it necessarily must use a continuous fiber to do so. The distinction made during the prosecution history is illustrative:

the fiber of the Goldman reference conducts laser energy to the movable mounting of a microscope far removed from the surgical site, at which point the energy is then transmitted through mirrors and the air to the surgical site. In contrast, the invention described in the '073 patent conducts laser energy from the laser source all the way to the surgical site. The distinction relates to where the fiber ends, not how the fiber is constructed. Both the plain language of the patent and the prosecution history are consistent with the use of several fiber segments or the combination of fibers and air to transmit the laser energy.

The phrase "a flexible, elongate fiber" is not a complicated description that has any specialized meaning within the relevant art, nor is it constrained by the specification or the prosecution history. Its meaning is well within the understanding of a lay juror and, therefore, the Court will construe it in accordance with its ordinary meaning to denote: "a flexible silica fiber, long in proportion to width."

3. **"means for reducing the absorption of laser energy at a wavelength of about 1.4 - 2.2 micrometers"** ('780 Patent, Claim 2), and **"low hydroxyl ion content"** ('073 Patent, Claims 2 & 7)

Cardiogenesis argues that these highlighted phrases do not comport with 35 U.S.C. § 112 and, as a result, the claims should be ruled indefinite. Given the similar arguments made with respect to each claim, the Court will address them together.

a. Section 112, ¶ 2 analysis

A claim is indefinite under 35 U.S.C. § 112 if

a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area.

Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008). Claims are not indefinite "merely because they present a difficult task of claim construction." Id. at 1249. Rather, a claim must be "insolubly ambiguous" to be ruled indefinite, id., and the party bringing the challenge bears the heavy burden of showing the insoluble ambiguity by clear and convincing evidence, id. at 1249. Importantly, claim construction "need not always purge every shred of ambiguity" and the resolution of some line-drawing problems may be left to the trier of fact. Acumed LLC v. Stryker Corp., 483 F.3d 800, 806 (Fed. Cir. 2007).

Cardiogenesis argues that the above phrases are indefinite because the specification does not provide 1) a specific definition of "low" (i.e., an amount in parts-per million of the hydroxyl ion content of 822W), 2) an explanation of the process by which the optical fiber must be "specially purified" to reduce the hydroxyl ion content or 3) a description of the 822W fiber's components. It asserts, therefore, that a person of ordinary skill in the art could not, from the patent, determine what constitutes a "low" hydroxyl ion content or identify the

corresponding structure in the specification that can provide the "means for reducing the absorption of laser energy."

The Court disagrees. A patent claim with an undefined relative term such as "low" is not indefinite unless the specification provides no standard against which to measure it. Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc., 731 F.2d 818, 826 (Fed. Cir. 1984); see also NexMed Holdings, Inc. v. Beta Tech., Inc., No. 2:06-CV-1014 TC, 2008 WL 2783522, at *4 (D. Utah July, 16, 2008) (finding "low DC voltage" not indefinite and construing it to mean "a voltage that results in a constant unidirectional flow not to exceed 30 milliamps"); Input/Output, Inc. v. Sercel, Inc., No. 5:06CV236, 2007 WL 6196070, at *30 (E.D. Tex. Dec. 19, 2007) (finding "low mechanical spring constant" not indefinite and construing it to mean "a mechanical spring constant that is not a high mechanical spring constant and that is sufficiently low so that sensitivity to low frequency forces is obtained"). Here, the specification provides an express standard against which to measure "low": the hydroxyl ion content must be low enough to "prevent[] the laser energy which is transmitted down the fiber from being highly absorbed in the fiber material," '073 patent, col 5:63-6:1; '780 patent, col. 6:3-7, so the claim is not indefinite.

A person of ordinary skill in the art could employ that standard to discern the boundaries of the claim. Dr. Sinofsky

testified that low hydroxyl ion content means, in the art, "low enough to be able to transmit 2-micron laser radiation 2 to 3 meters," and that a quick test can be performed to determine whether a fiber meets that criterion. Likewise, Michael Dumont, Dr. Sinofsky's former laboratory assistant, testified:

it was relatively straightforward to indirectly determine whether the OH content was low enough by measuring the mid-infrared transmission through the fiber.

A term is not indefinite if "a person of ordinary skill in the art could determine the specific amount without undue experimentation," Geneva Pharm., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003), so, for that additional reason, the phrases at issue are not indefinite.

The manner in which Dr. Sinofsky obtained the 822W fiber from Spectran underscores that point. After testing a number of fibers and finding none with characteristics suitable for transmitting laser energy directly to a surgical site, Dr. Sinofsky asked Dr. Peter Schultz at Spectran for an "ultralow OH fiber." Dr. Schultz did not ask Dr. Sinofsky for the exact percentage in parts-per million or throw up his hands at the blatant ambiguity of the request. He understood what Dr. Sinofsky meant and placed an order for 822W fiber. That, as the Federal Circuit has made clear, is all the statute requires.

b. Section 112, ¶ 6 analysis

Cardiogenesis further contends that "means for reducing the absorption of laser energy at a wavelength of about 1.4 - 2.2 micrometers" is indefinite for failing to disclose adequately the structure used to perform the recited function.

Claims written in means-plus-function form must comply with 35 U.S.C. § 112, ¶ 6:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

In a § 112, ¶ 6 analysis, the Court must first identify the function of the claimed limitation and then identify the structure disclosed in the specification that performs the claimed function. Telemac Cellular Corp. v. Topp Telecom., Inc., 247 F.3d 1316, 1324 (Fed. Cir. 2001). If the specification does not contain an "adequate disclosure" of the structure, the patent violates § 112, ¶ 6 and the claim should be found indefinite. In re Donaldson Co., 16 F.3d 1189, 1195 (Fed. Cir. 1994).

The function expressed in the '780 Patent is "means for reducing the absorption of laser energy at a wavelength of about 1.4-2.2 micrometers." CardioFocus submits that the phrase should be construed to cover the following corresponding structure:

specially treated fiber that has been purified to reduce the concentration of hydroxyl ions including fused silica optical fiber part no. 822W manufactured by Spectran

Corporation and equivalents thereof.

That structure is adequately described in the specification, CardioFocus explains, as Holmium, Erbium or Thulium lasers used with a fiber with a low enough hydroxyl ion concentration to transmit laser energy in the 1.4-2.2 micrometer wavelength range through an optical fiber to a surgical site, while "preventing the laser energy . . . from being highly absorbed in the fiber material." '780 Patent, col. 6:5-7. The specification goes on to provide an example of the kind of fiber covered:

A fiber which is suitable for use with the illustrative embodiment is a fused-silica fiber part no. 822W manufactured by the Spectran Corporation located in Sturbridge, Mass.

'780 Patent, col. 6:7-10.

Cardiogenesis responds that plaintiff's construction fails to meet the requirements of § 112, ¶ 6 because the specification does not disclose the process for making "specially purified" optical fibers or particularly describe their characteristics. It is not enough, Cardiogenesis asserts, to point to a specific product instead of describing its characteristics because the product may cease to be commercially available.

Cardiogenesis fails to grasp, however, that the patents-in-suit describe a more effective way to transmit laser energy to a surgical site using existing fiber optic technology. They do not purport to invent a new kind of fiber and thus need not describe the process for making it. CardioFocus must show only that an

ordinary person skilled in the art would be able to identify a fiber with low hydroxyl content, not that the person would be able to reproduce that fiber. See Tech. Licensing Corp. v. Videotek, Inc., 545 F.3d 1316, 1338-39 (Fed. Cir. 2008) (holding that use of term "black box" did not render the claim indefinite because that term was known in the field to represent video standard detector circuitry); Intel Corp. v. VIA Techs., Inc., 319 F.3d 1357, 1366 (Fed. Cir. 2003) (holding that generically defining the structure as "core logic," without explaining its circuitry or how it is modified, did not render the claim indefinite because the patented invention could function with any core logic); S3 Inc. v. NVIDIA Corp., 259 F.3d 1364, 1370-71 (Fed. Cir. 2001) (holding that a claim was not indefinite for using the term "selector" because it was a standard component and its structure was well known in the art).

CardioFocus points to a specific product that can be used to reproduce its invention, the 822W fiber manufactured by Spectran, so a person skilled in the art would have no trouble identifying the structure. Even if the product were no longer commercially available, a person of ordinary skill in the art could easily order another brand of ultralow OH fiber or test various fibers to identify one that fits the criteria.

In sum, the claims satisfy the requirements of 35 U.S.C. § 112 and are not indefinite.

**5. "coupling with" ('073 Patent, Claim 7) and
"coupled to" ('780 Patent, Claim 2)**

Cardiogenesis argues that the terms "coupling with" and "coupled to" necessarily require a physical connection and, with that in mind, the Court should define those terms as "the physical connection between the proximal end of the elongate fiber with the output of the energy source."

The Federal Circuit has held that the unmodified term "coupled" does not automatically imply a physical connection and has counseled courts against reading such a limitation into the term absent contrary evidence in the intrinsic record. See Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d 985, 992 (Fed. Cir. 1999). Finding no such contrary evidence here, this Court will not impose a physical connection limitation on the clear meaning of "coupled" or "coupling."

**6. "A system for transmitting laser energy via a
[sic] optical fiber to a surgical site" ('073
Patent, Claims 2 & 7)**

Cardiogenesis defines the phrase as:

A surgical system that is designed for biological tissue removal and/or repair in a living body that utilizes a continuous segment of silica fiber that extends from the source of laser energy to a site within the body where the biological tissue is removed and/or repaired.

CardioFocus counters that the phrase does not need to be construed at all because it is the preamble to Claim 1 of the '073 patent and not a limitation. Cardiogenesis replies that the

preamble requires construction by the Court in this case because the preamble language "via [sic] a optical fiber" was added to distinguish prior art references which taught laser energy transmission through air.

A preamble should not be construed where it does not state any new limitation that is not in the body of the claim but "merely states, for example, the purpose or intended use of the invention." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999). It need only be construed when, read in the context of the entire claim, it recites information that is "necessary to give life, meaning, or vitality" to the claim, such as when 1) it is essential to understanding the limitations or terms in the claim body, 2) it recites additional structure or steps underscored as important by the specification or 3) a party relied on it during the prosecution to distinguish the claimed invention from prior art. Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808-09 (Fed. Cir. 2002).

Putting aside whether the preamble language "via a [sic] optical fiber" was intended to "distinguish," as Cardiogenesis asserts, or "merely clarify," as CardioFocus maintains, it should not be read as a limitation because it does not add any term that is not present in the body of the claim. In fact, immediately after the preamble, Claim 1 describes the invention as "a flexible elongate optical fiber for conducting laser energy from

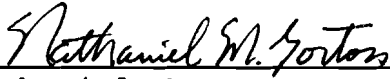
a proximal end of said fiber to a surgical site," a mirror image of the preamble terms. Because the preamble language is not "necessary to give life, meaning, or vitality" to the claim, it will not be construed.

ORDER

For the reasons set forth in the foregoing Memorandum, the disputed claim terms are construed as follows:

1. *a hollow elongate surgical instrument having at least one lumen* ('780 Patent, Claim 2) means "a hollow surgical instrument, long in proportion to width, having at least one hole";
2. *a flexible, elongate fiber* ('780 Patent, Claim 2) and *a flexible, elongate optical fiber* ('073 Patent, Claim 7) mean "a flexible silica fiber, long in proportion to width";
3. *means for reducing the absorption of laser energy at a wavelength of about 1.4 - 2.2 micrometers* ('780 Patent, Claim 2) is construed to cover the claimed function. The structure that performs that function is set forth in the patent specification: "fiber that has been purified to reduce the concentration of hydroxyl ions including fused silica optical fiber part no. 822W manufactured by Spectran Corporation";
4. *low hydroxyl ion content* ('073 Patent, Claims 2 & 7) means "hydroxyl ion content low enough to prevent laser energy from being highly absorbed in silica fiber";
5. *coupling with* ('073 Patent, Claim 7) and *coupled to* ('780 Patent, Claim 2) do not require construction;
6. *A system for transmitting laser energy via a [sic] optical fiber to a surgical site* ('073 Patent, Claims 2 & 7) does not require construction.

So ordered.



Nathaniel M. Gorton
United States District Judge

Dated November 3 , 2011